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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/380,932	01/18/2000	GREG FIRTH	28911/35930	3270

7590

09/24/2003

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EXAMINER

LACOURCIERE, KAREN A

ART UNIT

PAPER NUMBER

1635

25

DATE MAILED: 09/24/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/380,932

Applicant(s)

FIRTH, GREG

Examiner

Karen A. Lacourciere

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 June 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 and 14-27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-10, 15 and 22-26 is/are allowed.
- 6) ☒ Claim(s) 11, 12, 21 and 27 is/are rejected.
- 7) ☐ Claim(s) 17-20 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on June 30, 2003 has been entered.

Claim Objections

The objections to claims 11, 21, and 22-25 are withdrawn in response to Applicant's amendments and arguments filed 06-30-2003.

Claim 19 is objected to because of the following informalities: Claim 19 is objected to because the spacing of the words is irregular, such that spaces occur inappropriately within words. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 19 and 20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claim 19 recites wherein at least one mismatch is selected, however, claim 19 depends from claim 17, wherein the method of claim 17 recites wherein the mismatches are discarded. It is unclear how a mismatch can be selected in claim 19, when an earlier step would require that such mismatches be discarded. Claim 20 is indefinite for the same reasons due to dependence on claim 19.

Claim Rejections - 35 USC § 102

The rejection of record of claim 15 as anticipated by Morgante et al. is withdrawn in response to Applicant's amendments filed June 30, 2003.

Claims 11, 12, 14 and 21 are maintained as rejected under 35 U.S.C. 102(b) as being anticipated by Morgante et al., WO 96/17082, for the same reasons of record as set forth in the previous Official Actions mailed 08/27/01, 2/14/01, 6/6/00, 05/28/02 and 02-26-2003.

Applicant's arguments filed June 30, 2003 have been fully considered but they are not persuasive.

Claims 11 and 12 as amended are drawn to a mixture of one or more VNTR alleles and their flanking regions, said mixture consisting essentially of a representative mixture of alleles of a chosen variable number tandem repeat (VNTR) sequence and their flanking regions on both sides, wherein each member of the representative mixture of alleles has an adaptor at each of its 3'-end and its 5'-end; wherein the mixture of alleles is representative of those which manifest a trait of interest.

Morgante et al. taught in Figure 11, and on page 18, lines 4-7, generation of genomic restriction fragments carrying an allelic repeat bordered at both ends by restriction site-specific adaptors, Ad_A and Ad_B. They thus taught the claimed mixture of VNTR alleles and their flanking regions (their alleles they called SSR regions, or "simple sequence repeat", see page 18, line 29) where the flanking regions have 3' and 5' adaptors. They taught wherein the SSR (VNTR) regions manifest a trait of interest on page 19, lines 3-5: "Simple sequence repeats are common in virtually all eukaryotic genomes studied and have been identified as useful tools for the study of genetic polymorphisms."

Claim 14 as amended is drawn to a composition consisting essentially of one or more copies of a single variable number tandem repeat (VNTR) allele and its flanking regions and an adaptor at each of its 3'-end and its 5'-end, said allele being characteristic of those which manifest a trait of interest.

As described above, Morgante et al. taught the a mixture, thus a composition of one or more copies of SSR (ie. VNTR) alleles having adaptor flanking regions at both the 5' and 3' end.

Claim 21 is maintained as rejected by Morgante et al. since the method comprises dividing genomic DNA of one or more members of a species of interest into fragments and ligating to each end of each fragment an adaptor thereby forming a mixture of adaptor-terminated fragments in which each 3'-end is blocked to prevent enzymatic chain extension (instant steps a) and b)), but only one of either of steps c) or

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d) is required by the claim 21. Since Morgante et al. teaches in figure 11 (and page 18, lines 4-7) instant steps a) and b), the formation of fragments having 5' and 3' adaptors, and further teaches in figure 11, the first composition, the PCR of the AdB and SSR region, which results in the mixture of instant step c), of 5'-flanking VNTR amplimers.

In response to the rejection of record of claim 21 under 35 USC 102 (b) as anticipated by Morgante et al., Applicant argues that Morgante et al. do not disclose contacting a mixture wherein each 3'-end is blocked to prevent enzymatic chain extension and therefore, does not meet all of the limitations of the claimed method. This is not found to be persuasive because the steps recited in the claimed method are in the alternative (see step c, line 4 "and/or") and therefore, the claim does not require that the mixture contacted be 3' end blocked.

In response to the rejection of record of claims 11, 12, 14 and 21 Applicant argues that the transitional phrase "consists essentially of" excludes the compositions taught by Morgante et al. because this phrase is meant to mean primarily composed of VTNR alleles and that the vast majority of fragments created by the restriction enzymes in the Morgante et al. methods would lack VTNR sequences and would not be enriched for VTNR sequences, as claimed. Applicant argues that the compositions disclosed by Mogante et al. contain many components that would materially effect the claimed compositions. This is not found to be persuasive because the claimed compositions do not require enrichment of VTNR sequences and "consists essentially of" is open language". Although the compositions of Morgante et al. comprise other components, in addition to the VTNR sequences, it does not appear that these other components

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would materially effect the claimed compositions. Applicant has not provided any reason to suggest that these compositions would be materially effected, rather has merely asserted such. Additionally, it is unclear where applicant derives the assertion that the majority of the genomic fragments taught by Morgante do not contain an VTNR sequence. Morgante teaches generation of the genomic fragments via restriction enzyme digestion, the same method used by applicant in the instant disclosure on page 15, lines 3-8: "The use of one or more restriction enzymes gives rise to uniform fragmentation of the genomic sample and constitutes the preferred technique. With judicious choice of restriction enzymes that cut frequently there is potential for generation en masse of every VNTR of the chosen type within a genome or pool of genomes since virtually all fragments will be sufficiently small for efficient amplification." Thus, the fragments of Morgante et al., generated via restriction enzyme (page 18, lines 4-7 of Morgante et al.), overlap in scope, and consist essentially of the fragments instantly claimed and disclosed since the instantly claimed fragments were also generated via enzymatic restriction digestion as "the preferred technique." (Instant specification page 15, lines 4-5)

Claims 16 and 27 stand rejected under 35 U.S.C. 102(b) as being anticipated by Nelson et al. for the same reasons of record as set forth in the Official Action mailed 08/27/01, 02/14/01 and 6/6/00 and 05/28/02 and 02-26-2003.

Applicant's arguments filed June 30, 2003 have been fully considered but they are not persuasive.

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Applicant traverses the rejection on page 12 of the amendment filed June 30, 2003. Applicants argue that the nucleic acids being treated in Nelson are digested genomic DNA, which do not consist essentially of a mixture of polymorphic alleles because the alleles would only form a minor portion of the mixture, which is enriched for polymorphic alleles.

This is not found to be persuasive because claim 16 does not require an enriched population of polymorphic alleles, but rather treatment of a mixture of polymorphic alleles. The language "consists essentially of" is open language and, therefore, it does not exclude the mixture used in the methods of Nelson et al. Thus, while it appears that applicant is interpreting the claim to the extent that the mixture of a trait of interest is limited to one VNTR allele trait of interest, the claim is drawn to use of a mixture of more than one polymorphic allele that is representative of "those which manifest a trait of interest." As such the teachings of Nelson et al., which start with a fragmented genomic population, provide use of a mixture of polymorphic alleles generated the same way as those instantly disclosed, ie. by restriction digestion of the genomic population. Claim 27 stands rejected for its dependency on claim 16, wherein the compositions used in the methods of Nelson et al. would comprise all of the components of the claimed kits and, therefore, would anticipate the claimed kits.

Allowable Subject Matter

Claims 1-10, 15 and 22-26 are allowed.

Claims 17,18, 19 and 20 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen A. Lacourciere whose telephone number is (703) 308-7523. The examiner can normally be reached on Monday-Thursday 7:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John L. LeGuyader can be reached on (703) 308-0447. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Karen A. Lacourciere
September 22, 2003

Karen Lacourciere
KAREN A. LACOURCIERE, PH.D.
PRIMARY EXAMINER